

AMENDMENT TO THE AMENDMENT  
IN THE NATURE OF A SUBSTITUTE TO H.R. 1108

OFFERED BY Mr. Buyer of Indiana

On page 129, after line, 2 insert the following (and make such conforming changes as may be necessary):

"Sec. 921. EFFECTIVE DATE

"This chapter shall not become effective until <sup>10</sup> years after the date of enactment of [the Family Smoking Prevention and Tobacco Control Act] in order to allow the Food and Drug Administration sufficient time to inspect every foreign facility engaged in the manufacture, preparation, propagation, compounding, or processing (as such phrase is defined in section 510(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(a)) of drugs that are imported into the United States."

[Buyer 41]

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OFFERED BY Mr. Buyer of Indiana

On page 129, after line, 2 insert the following (and make such conforming changes as may be necessary):

"Sec. 921. EFFECTIVE DATE

"This chapter shall not become effective until 5 years after the date of enactment of [the Family Smoking Prevention and Tobacco Control Act] in order to allow the Food and Drug Administration sufficient time to certify that the Office of Regulatory Affairs of the Food and Drug Administration has sufficient staff, resources, and technology at the 12 international mail facilities in the United States to inspect at least 90 percent of the packages of drugs and devices (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (201 U.S.C. 321)) being imported into the United States through such facilities."

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OFFERED BY Mr. Buyer of Indiana

On page 129, after line, 2 insert the following (and make such conforming changes as may be necessary):

“Sec. 921. EFFECTIVE DATE

“This chapter shall not become effective until 3 years after the date of enactment of [the Family Smoking Prevention and Tobacco Control Act] in order to allow the Food and Drug Administration sufficient time to certify that the Food and Drug Administration is able to achieve the goals identified in the letters described in section 101(c) of the Food and Drug Administration Amendments Act of 2007 (21 U.S.C. 379g note; relating to the Prescription Drug User Fee Amendments of 2007).

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“Sec. 921. EFFECTIVE DATE

“This chapter shall not become effective until 3 years after the date of enactment of [the Family Smoking Prevention and Tobacco Control Act] in order to allow the Food and Drug Administration sufficient time to certify that the Food and Drug Administration is able to achieve the goals identified in the letters described in section 101(c) of the Food and Drug Administration Amendments Act of 2007 (21 U.S.C. 379g note; relating to the Prescription Drug User Fee Amendments of 2007).

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OFFERED BY Mr. Buyer of Indiana

On page 129, after line, 2 insert the following (and make such conforming changes as may be necessary):

"Sec. 921. EFFECTIVE DATE

"This chapter shall not become effective until 3 years after the date of enactment of [the Family Smoking Prevention and Tobacco Control Act] in order to allow the Food and Drug Administration sufficient time to certify that the Food and Drug Administration is able to achieve the goals identified in the letters described in section 201(c) of the Food and Drug Administration Amendments Act of 2007 (21 U.S.C. 379i note; relating to the Medical Device User Fee Amendments of 2007).

**AMENDMENT TO THE AMENDMENT IN THE  
NATURE OF A SUBSTITUTE TO H.R. 1108  
OFFERED BY MR. Rogers**

Page 129, after line 2, insert the following (and make such conforming changes as may be necessary):

1 **“SEC. 921. EFFECTIVE DATE.**

2       “‘This chapter, title I of the Family Smoking Preven-  
3 tion and Tobacco Control Act, and the amendments made  
4 by such title shall not become effective until the Secretary  
5 of Health and Human Services certifies that the Food and  
6 Drug Administration is able to review and approve or dis-  
7 approve all applications received by the Center for Bio-  
8 logics Evaluation and Research that have been received  
9 by that office over the 10-year period preceding the date  
10 of enactment of the Family Smoking Prevention and To-  
11 bacco Control Act.”.